HIT Policy Committee & HIT Standards Committee

PCAST Workgroup, February 15, 2011

Panel 3, Population Health

Written Testimony by Joyce C. Niland, Ph.D.

Associate Director & Chair, Information Sciences, City of Hope

Thank you for this opportunity to comment on the "Report to the President, Realizing Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward". The achievement of a universal Electronic Heath Record (EHR) will confer many benefits both to personalized healthcare, and to facilitating population-based research into the most efficacious treatment approaches. The President's Council of Advisors on Science and Technology (PCAST) report does a very good job of framing up the background and complexity of introducing innovative healthcare technology into the healthcare arena, and summarizing a viable path forward to achieve this elusive goal. However the solution to these highly complex issues is extremely difficult, as recognized by the panel.

I have been asked to comment on the PCAST report particularly with respect to the impact on population health and research. As background, I serve as an Associate Director of City of Hope's National Cancer Institute (NCI)-designated Comprehensive Cancer Center, and as endowed Chair of the Department of Information Sciences at City of Hope. I also currently serve as Principal Investigator for 3 national coordinating centers: for outcomes research across 21 National Comprehensive Cancer Network (NCCN) institutions, for a research consortium for human pancreatic islet cells for treating Type I diabetes, and for a national consortium in intestinal stem cell research.

My responses to the themes/questions posed to the panel relate to both the overall premise put forth by the report, and also focus on Chapter VII. Health Data and the Research Opportunity. Overall I agree with the "bottom line" of this chapter for advancing healthcare, namely: "A national health IT infrastructure will enable new kinds of research and will also create opportunities for the faster coupling of research to clinical practice." However the solutions proposed appear to be somewhat incomplete, and will not be able to fully support enhancing patient care and advancing biomedical research, for the reasons which follow.

Semantic Interoperability: The technological approach of metadata tagged data elements seems sound and appropriate to achieving interoperable exchangeable health information within EHRs. However focusing on standardized data exchange formats is only one piece of a very complex puzzle. Standardizing how to deliver the data addresses

the syntactic interoperability issue. However this approach does not fully address the issue of semantic interoperability, the key to common understanding and integration of data across multiple organizations, care providers, patients, settings, and even languages. This level of interoperability is critical, particularly with respect to reuse of clinical data for population, outcomes, comparative effectiveness research, and facilitating the gold standard clinical trial.

Without standard coded reusable medical data, medical record information will not be usable or useful for research. For such research purposes it is necessary to capture full coded information on past medical history, race/ethnicity, health insurance, preferred/primary language (for disparities research), presenting characteristics, co-morbid conditions, prior treatment, diagnoses, current prescribed and actually delivered treatments, follow-up tests, any adverse events or complications, and finally and ultimately the success of these treatments and the outcomes, both in terms of biological efficacy, overall effectiveness, quality of life, cognitive, spiritual, familial and health outcomes, and of course, survival.

Often technology proponents point to the advances and gains made in other industries, marketing, retail, airlines, banking. However health record information and the human phenome is a much more complex complicated topic than these other domains, and it remains extremely difficult to capture the essence of the human condition, treatments and outcomes in a standard way, so that data can be pooled and analyzed across populations of patients.

For example, what constitutes a “diagnosis”? Do we refer to the presenting symptoms? Suspected diagnosis? Laboratory documented findings? Final pathological diagnosis? Concurrent conditions? How shall we code all of this information, and how can the busy caretaker render coded discrete fields to capture this information during the course of a busy, time-constrained, typically 5-10 minute medical appointment?

To be able to mine data for research purposes, we need common data standard content, in coded discrete data elements, to be able to “speak the same language” when synthesizing medical information for research, and indeed for improved, more efficient, transportable health care. The standards for the phenomic, or biologic, data, and for medical diagnoses and treatments are myriad and have not been well established in a sustainable practical way.

The PCAST report seems incomplete in that it does not address the issue of common vocabularies for the coded data elements, nor rules for combining data elements into meaningful expressions. Vocabulary standards such as LOINC, SNOMED CT, RxNORM, ICD need to be a part of the ultimate solution. Such processes are required to enable decisions support, reasoning, and quality assessment of the content of information interchange.

The idea of using a collection of semantically rich tagged data elements as a means of exchanging health information has been the pursuit of the Health Level 7 (HL7) standards setting body for two decades now. The HL7 Reference Information Model (RIM) can serve as the foundation for the universal language for health information exchange, and should become the foundation for deriving data exchange specifications using XML.

Facilitating Research: The PCAST report discusses the potential for more efficiently linking patients to clinical studies using the EHR. There is indeed an excellent opportunity afforded to us by this form of electronic data capture. How can we use medical record data to more rapidly screen patients for possible existing clinical trials from which they may benefit?

Only if a core set of pragmatic condensed eligibility criteria regarding those protocols are coded about the study at the time it is registered to an international web-based registry (e.g. min and max allowable range, non-allowable organ status or prior treatment), and then these same data elements are coded about the patient when he/she first presents for care, could automated decision support be invoked to filter out inappropriate trials, and recommend the short shopping cart list of studies that should be considered for a given patient.

The Clinical Data Interchange Standards Consortium (CDISC) Protocol Representation Group has a project devoted to just this encoding of core eligibility criteria. The ASPIRE project (Assessing Standardized Protocol Inclusion Requirements for Eligibility) has determined a core set of pan-disease and disease specific eligibility criteria, which if adopted universally for registering protocol eligibility requirements in a coded fashion, could greatly speed filtering available protocols for patients. The equivalent data elements from the patients' perspective would need to be routinely captured in coded fashion in the EHR to make this protocol-patient filtering process successful.

The PCAST report also mentions the opportunity to facilitate surveillance and public health monitoring via the emerging EHR data. However aggregation, data mining and synthesis of such data is only possible if the information has been coded at a highly granular level using common vocabularies and ontologies.

Practicality of EHR Data Capture: In spite of advances in EHRs to date, the human computer interface that allows rapid valid translation of medical information into discrete standard codes has been highly elusive. Caregivers simply do not have the time to interrupt their patient encounter to achieve this goal. Staring at tablets and in room computers while 'pointing and clicking' interferes with the face to face critical human encounter that needs to take place for a rich medical encounter.

The PCAST report rightly acknowledges that practicing physicians are extremely busy, and not always the ideal collectors of patient data for research purposes. The report discusses the tradeoffs of collecting research-quality data against the possible burdens to the healthcare providers. While computerization is intended to make physicians more efficient and ensure better care for patients, doctors have estimated that their productivity plummets by about 30% as they learn to cope with new EHRs.

At this juncture as we attempt to introduce a new paradigm of the practice of medicine that involves utilization of a complex EHR by practicing physicians, to achieve coded reusable standardized data at the point of care may require a new role in medicine, in terms of a "physician extender". An emerging healthcare role is that of "Chief Medical Scribe", filling a niche as doctors make the unsettling transition from paper charts to EHRs.

The Scribe would be at the caregiver's side during the patient encounter, rapidly entering keystrokes for the information being heard during the visit. Scribes can listen intently as MDs examine patients, record treatment plans in a laptop computer, and follow up on prescriptions, lab tests, consultations with specialists, and anything further ordered by the MD. Through reviewing subsequent dictations, the Scribe could further could additional nuances to the diagnosis, prescribed care, and outcomes yielded and code these data into the EHR in a standardized manner. While the emergence of this new role is newly unfolding in today's transition to the EHR, it will be interesting to note whether it disappears as the next generation of MDs comes into their own.

Universal Patient Identifier: It is not clear how the proposed approaches in the PCAST report will eliminate the need for a universal patient identifier. Incorrect record linkage is another major hurdle with EHRs, both for patient care and research needs. How will the systems know the appropriate linkage between medical records for the same individual, particularly across a myriad of healthcare organizations, providers, and EHRs that may contain information on the same person? Relying on identity resolution technologies and probabilistic person matching algorithms are imperfect, and do not resolve to identify individuals with sufficient certainty to be used in healthcare nor biomedical research.

In summary, while the PCAST recommendations are along the right vein, the universal language as proposed is not sufficient, but rather a complete semantic framework is required, with a common data model, terminology services, ontology, rules expression language, and identity resolution capabilities.